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April 29, 2010

Rep. Edward J Markey
House of Representatives
Committee on Energy and Commerce
Subcommittee on Energy and Environment
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Rep. Markey,

The following information has been generated as a response to your request regarding treatment of patients with radio-isotopes.

1. **How many I-131 licensee facilities are overseen by your State?**
   New Mexico regulates fifty-three (53) licensees that administer Iodine 131. Seventeen (17) licensees administer Iodine 131 in therapeutic and diagnostic quantities and thirty-six administer Iodine 131 in diagnostic quantities only (note: information was extracted as of March 24, 2010).

2. **How often does your State perform sampling inspections each of these I-131 licensee facilities?**
   Medical Institutions Broad Scope Licensee (BM) inspection is annual; Medical Institutions Licensee (MI) twenty-eight (28) and Medical Private Practice Licensee (MD) twenty-four (24) inspections are two years.

3. **What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.**
   The State has adopted the NUREG 1556, Vol. 9, Appendix U, (U-12), guidance criteria, for use during licensing and inspection of Iodine-131 review and inspection of licensees, and 20.3.7.703.I NMAC regulations, effective April 29, 2009. **(See attached Medical-Nuclear Medicine Inspection Record).**

4. **NCRP 155 includes "Radiation safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household,**

using two rinse cycles; to wipe down the telephone with paper towels and than discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?

The latest update of our regulation was completed in April 2009 and includes 20.3.7 Medical Use of Radionuclide's. The following information is required to be know by all our licensee's and is available on our WEB site at:

http://www.nmcpr.state.nm.us/nmac/parts/title20/20.003.0007.htm

Implementation and compliance with 20.3.7 NMAC and NUREG 1556, Vol. 9, Appendix U: In accordance with 20.3.7.703.I NMAC, (1) A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent (TEDE), to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 millisieverts), (the licensee may use the most current revision of the NRC guidance NUREG 1556, Volume 9, "consolidated guidance about materials licenses: Program specific guidance about medical licenses", appendix U which describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 millisieverts). (2) A licensee shall provide the released individual or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as reasonable achievable (ALARA), if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 millisievert). If the TEDE to a nursing infant or child could exceed 0.1 rem (1 millisievert), assuming there is no interruption of breast-feeding, and the instructions must also include: (a) guidance on the interruption or discontinuation of breast-feeding; and (b) information on the potential consequences, if any, of failure to follow the guidance. (3) A licensee shall maintain a record of the basis for authorizing the release of an individual, in accordance with 20.3.7.715.J NMAC. (4) A licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with 20.3.7.715.J NMAC. (See sample, licensee's instruction for Release of patients).

Also included under **20.3.7.709 SAFETY INSTRUCTIONS AND PRECAUTIONS FOR USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED:** In addition to the requirements in 20.3.10.1002 NMAC, the licensee shall provide the following.

A. Safety Instructions. A licensee shall provide radiation safety instructions initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under Subsection I of 20.3.7.703 NMAC. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include:

(1) patient or human research subject control;

(2) visitor control, including:

(a) routine visitation to hospitalized individuals in accordance with Paragraph (1) of Subsection A of 20.3.4.413 NMAC; and

(b) visitation authorized in accordance with Subsection F of 20.3.4.413 NMAC;

(3) contamination control;

(4) waste control; and

(5) notification of the radiation safety officer, or their designee, and an authorized user if the patient or the human research subject has a medical emergency or dies.

B. Record Keeping. A licensee shall retain a record of individuals receiving safety instructions, as specified in Subsection A of this section, in accordance with Subsection O of 20.3.7.715 NMAC.

C. Safety Precautions. For each patient or human research subject who cannot be released under Subsection I of 20.3.7.703 NMAC, a licensee shall:

(1) quarter the patient or the human research subject either in:

(a) a private room with a private sanitary facility; or

(b) a room, with a private sanitary facility, with another individual who also has received therapy with unsealed radioactive material and who also cannot be released under Subsection I of 20.3.7.703 NMAC;

(2) visibly post the patient's or human research subject's room with a "Radioactive Materials" sign;

(3) note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room;

(4) either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle the material and items as radioactive waste; and

(5) a licensee shall notify the radiation safety officer, or their designee, and an authorized user, as soon as possible if the patient or human research subject has a medical emergency or dies.

5. **In the past ten years, how many times has your State, as part of the inspections it conducts, requested documentation from the licensee facilities that detail the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?**

The State inspector reviews records for therapeutic, Written Directive required administrations, during the course of every inspection. Documentation is reviewed and copies are requested for any non-compliance or deficiencies found. Documents for the release of patients administered Iodine-131 requiring a Written Directive are reviewed when conducting inspections annually or every two years depending on the inspection frequency. The licensees providing medical use therapies are required to have a Radiation Safety Committee to oversee the use of radioactive materials, the approval of the authorized user qualifications, and annual review of patient's records administered therapeutic radionuclide's and procedures and corrective actions , if applicable. There are no records from past inspections indicating a release to a hotel, and only one where a patient may have been released in violation of release limits (see attached NOV patient release).

6. **In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from the licensee care?**
For every inspection of Iodine-131 requiring Written Directive administrations, inspectors evaluate the licensee's patient release policy to verify compliance with state requirements (i.e. licensee knowledge about release criteria, maintain appropriate records to document the basis for authorizing the individual's release, and provide adequate instructions to patients).

7. **In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.**
During a recent inspection, of a Medical Institution, a Notice of Violation letter was issued for non-compliance with 20.3.7.703.I (1) NMAC authorizing the release from its control of patients who did not meet the criteria for release as specified in this provision, and non-compliance with 20.3.7.703.I (3) NMAC for the licensee not maintaining accurate records of the basis for authorizing the release of patients. No other violations noted for Written Directive administration records at other licensee facilities previously inspected. (see attached NOV patient release)

8. **In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant women sleeping on the other side of a wall. Do you agree?**
All of the medical institutions (BM & MI) and medical private practice (MD) facilities in the State do not recommend the patient stay at a hotel but they cannot guarantee the patient is not staying at a hotel after treatment is received. Their policy would implement hospitalization of the patient, who could not meet the criteria for release, at their facility or that of a previously approved medical institution.

9. **Has your State ever attempted to determine how many patients treated with I-131 are (a) sent home, (b) sent to a hotel, or (c) kept in the hospital for additional time? If so, please provide the results. If not, why not?**
The state does not keep a specific tally of patients treated, sent home or to hotels or that are kept in the hospital. The State inspector reviews a sample of patient documents to determine I-131 release criteria during inspections and, if documents are found deficient, the State inspector notifies the licensee of the deficiencies during the exit interview and follows up with a Notice of Violation requiring the licensee to respond within 20 days of receipt of the Notice of Violation with measure taken to correct the deficiencies.

10. **In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations**

were not performed when they were required? Please provide reports and documentation relating to those cases.

As discussed in previous responses above, State inspectors evaluate the licensee's program for patient release to verify compliance with state regulations that are compatible with NRC requirements. In patients with doses in excess of default limits, a Notice of Violation is issued requiring measures be taken to correct the deficiencies. (see attached NOV patient release)

11. **What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?**

    The guidance in NUREG-1556, Volume 9, Revision 2, Appendix U describes in general terms how licensees can meet this performance-based objective. During the course of completing inspections, to the best of our knowledge, no medical institution has indicated they release patients to hotels; therefore there is no disclosure rule for patients required. (See attachments from licensees)

12. **Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.**

    We have not issued an advisory or guidance warning licensees not to send patients to hotels. We have in April 2009, in 20.3.7.703.I NMAC incorporated by reference the current revision of the NRC guidance NUREG-1556, volume 9, "*consolidated guidance about materials licenses: program-specific guidance about medical licenses*", describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 millisieverts).

13. **Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?**

    Yes. Records are required to contain the calculations for Total Effective Dose Equivalent (TEDE) calculated for activity administered, occupancy factor at 1 meter; using biological or effective half-life; or considering shielding by tissue. Instructions are required if radiation dose should result in Effective Dose Equivalent (EDE) exceeding 0.5 rem (5 mSv). If a patient cannot meet the requirements on release conditions, the licensee will hospitalize the patient.

14. **Please provide copies of all correspondence, including e-mails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radionuclide's.**

    The only correspondence we are aware of regarding release of patients, between the NRC and our state occurred during the process of revising our state regulations to meet compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-200. On April 30, 2009 the state regulations 20.3.7 NMAC "Medical use of Radionuclide's" became compatible with the equivalent Nuclear Regulatory Commission rules in 10CFR35, and NUREG 1556, vol. 9 guidance, (i.e. Program-Specific Guidance about Medical Use Licenses).

15. **Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspection found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.**
    No instances were found in which documents relating to patient release were found to be missing, but one was found to be inadequate and unclear during the course of a sampling inspection (see attached NOV patient release). No instances were identified where a patient was released and sent to a hotel after treatment.

This information was prepared by New Mexico Environment Department, Radiation Control Bureau staff. They spent appoximately 55 hours on research and in preparation of this information. The staff worked diligently and deserve recognition of the time spent while continuing to conduct their regular work functions. The staff include Mr. Michael Ortiz, Ms. Margret Roybal, and Mr. Walter Medina.

Finally, if there is additional information that you may need please contact me at (505) 476-8605.

Sincerely,

Carlos Romero
Environmental Health Division Director

Enclosures

cc: Ron Curry, New Mexico Environment Department Secretary

State of New Mexico
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Governor

DIANE DENISH
Lieutenant Governor

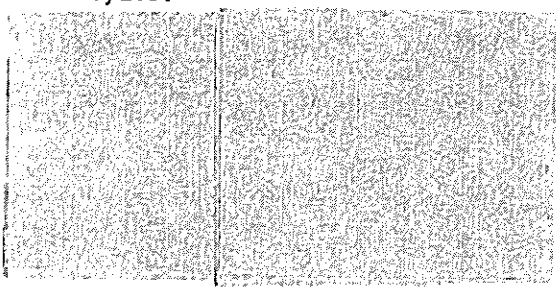
RON CURRY
Secretary

CARLOS ROMERO
Director

CERTIFIED MAIL—RETURN RECEIPT REQUESTED

NOTICE OF VIOLATION

March 5, 2010



This letter documents a routine inspection conducted on February 16 through 19, 2010 by team of inspectors of activities authorized by your Radioactive Material License The inspection was an assessment the activities authorized under the aforementioned license as they relate to radiation safety and compliance with the New Mexico Radiation Protection Regulations, 20.3 NMAC.

During this inspection, the following deficiencies were noted:

1) Contrary to 20.3.4.404.C NMAC, the licensee does not review the entire Radiation Protection Program associated with all activities authorized under the license. Specifically, the licensee does not include in its annual review required under this provision, a review of the procedures, documentation, and practices of the UNM Hospital Nuclear Medicine Department and the UNM Cancer Center.

2) Contrary to 20.3.4.441.A(2) NMAC, the licensee does not maintain records of the annual audit review for certain aspects of the Radiation Safety Program. This deficiency distinguishes between conducting an audit and documenting it. Specifically, the licensee is only documenting quarterly checks of the surveys required to be conducted by the permittees of the licensee. The licensee does not document a review of procedures (SOPs), checks of inventory, checks of training records, checks of condition of survey meters and their calibration records, checks of dosimetry program, and all other aspects of a Radiation Protection Program.

3) Contrary to 20.3.7.703.I(1) NMAC, the licensee may have authorized the release from its control of patients who do not meet the criteria for release as specified in this provision. Specifically,

CANCER INSTITUTE
of New Mexico

I-131 Therapy
Written Directive

Physician Orders

Patient Name: _____

Patient ID Sticker

Hospital Number: _____

Prescription: _____ mCi I-131

Administration Orders

- o **Outpatient Administration**, Dose < 200 mCi for Post Thryoidectomy Patient.
  (Patient-Specific Factors per Regulatory Guide 8.39, Appendix B, E=0.25)
- o **Outpatient Administration** (Other Patient-Specific Factors – Document on Back)
- o **Inpatient Administration**, Arrange for hospital room; Release after Dose Rate < 7 mR/hr at 1-meter
  (Regulatory Guide 8.39, Table 1, Column 2)
- o Other: _____

Authorized User Signature: _____ Date: _____

Following Section to be completed by Physics on Administration Day

Verification of Patient Identification (Check Two Methods Used)

o Ask Name o Check Birth Date o Check Address o Check SSN

o Check Signature o Check ID Bracelet o Check ID Card o Check Insurance

Administration Date: _____ Administration Time: _____

Person Administrating Dose: _____ Room Exposure rate at finish: _____ mr/hr

Administered Dose per Prescription: _____ (Initial of Physicist/Dosimetrist)

Recommendations to Reduce Radiation Exposure to Others

Patient Name:_____ *Patient ID Sticker*

ID# _____

Date: _____

For the next 4 days (after administration):

1. Maintain distance from others (approximately 6 feet). Brief contact is OK (example: hugs, kissing on cheek, etc.).
2. Sleep alone (at a minimum, 2 days).
3. Have children/pregnant women stay with friends/relatives (if possible).
4. Limit unnecessary visitors.
5. Avoid public events of long duration. (e.g., movie theaters, restaurants, church, family gatherings).
6. Avoid prolong automobile trips with others.
7. Avoid public transportation when possible (buses, planes).
8. If possible, have sole use of bathroom. Flush at least twice after use.
9. Shower at least twice a day.
10. Avoid preparing food for others if possible. Wash hands often if preparing food for others.
11. Drink plenty of fluids.

I, _____, understand that following these instructions minimizes the radiation exposure to others. I understand that I should follow these instructions following my treatment. All of my questions have been fully answered and explained to me.

_____

Patient or Legal Guardian Signature

_____

Radiation Safety Officer or designate

CANCER INSTITUTE
of New Mexico

Outpatient I 131 Therapeutic Administrations

I. Purpose

This procedure establishes requirements providing high confidence that outpatient I-131 administrations are performed in a safe an accurate manner by the Cancer Institute of New Mexico.

II. References

A. NRC Regulatory Guide 8.39, Release of Patients Administered Radioactive Materials, April 1997.

B. NRC NUREG-1492, Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material, April 1996.

III. Patient Interview

A patient-specific calculation will be performed to determine the maximum likely dose to a non-treated individual. **Appendix A** calculates the administration doses where temporary inpatient isolation must be provided.

A. The Radiation Oncologist (i.e., Authorized User) will interview the patient to determine if they are suitable candidates for outpatient treatment. The **Outpatient I-131 Treatment Interview** (Attachments) provides the information to be requested.

B. The Radiation Oncologist will complete the upper portion (Physicians Orders) of the **Written Directive** Form.

C. Review the dose prescription against the following Table. Patients with dosages exceeding these limits will not be treated as outpatients.

Maximum Outpatient I-131 Sodium Iodide Dosages

Patient Status	Maximum Outpatient Dosage (mCi)
Post Thyroidectomy	**200**

IV. Patient Release

A. Prior to administration, Physics personnel will verify the dosage and patient identity and complete the lower portion of the **Written Directive**.

B. Physics personnel will review the **Recommendations to Reduce Radiation Exposure to Others** with the patient prior to release (**Attachments**).

C. Ensure that the patient acknowledges the receipt of instructions by signature on the bottom of the form. Keep the original completed form for radiation safety records and provide the patient copies for reference.

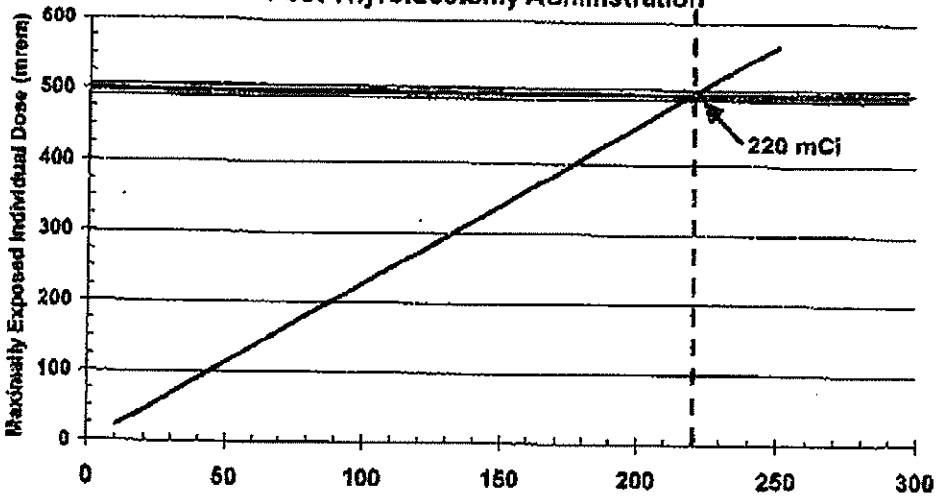
V. Record Requirements

A. All records generated by this procedure will be maintained for at least 3 years

B. Documents that are to be discarded will be transferred to the RSO for disposal.

Appendix

Figure 1: Maximally Exposed Individual Dose Calculation Post Thyroidectomy Adminstration



5. Based on the delineated Patient-Specific Calculations, Table 2 provides the maximum I-131 sodium iodide doses that may be administered as an outpatient procedure.

Table 2: Maximum Outpatient I-131 Sodium Iodide Dosages

Medical Condition	Maximum Outpatient Dosage (mCi)
Thyroid Carcinoma (post thyroidectomy)	**200**

6. A review of Equation B-5 indicates that the maximal dose to a non-treated person is very sensitive to the thyroidal compartment uptake fraction F_2. Table B-1 from reference A provides a 5 percent value as "an upper limit postthyroidectomy for thyroid cancer (Ref. A)."

Table 3: Residual Thyroid Limit for Outpatient Treatments

Maximum Outpatient Dose Using Standard Assumptions (mCi)	Maximum Residual Thryoid Uptake
220	**5%**
200	**7%**
175	**10%**
150	**13%**

The standard dose for postthyroidectomy patients at Albuquerque Regional Medical Center is 150 mCi. The residual thyroid uptake percentage necessary to yield a 500 mrem dose to a non-treated person via Equation B-5 is 13%. It is not credible that a postthyroidectomy patient will have 13% residual thyroidal tissue uptake.

CANCER INSTITUTE
of New Mexico

Outpatient I-131 Treatment Interview
NaI Dosages < 33 mCi

Patient Name: _____

ID#: _____

Interview Date: _____

Planned Dose (mCi): _____

Patient ID Sticker

Any "Yes" answer to the following questions indicates that the patients can not be released per this procedure.

Note: The patient may be a suitable candidate for outpatient therapy under restrictions (see alternate procedures). Refer to the RSO or designee for special circumstances.

Is the Intended Dose greater than 33 mCi?	☐ Yes ☐ No
Is the administered radiopharmaceutical any form other than NaI?	☐ Yes ☐ No
Is there a chance that the Patient is pregnant?	☐ Yes ☐ No or N/A
Patient planning to continue breast feeding after administration?	☐ Yes ☐ No or N/A
Do you have significant problems with urinary incontinence?	☐ Yes ☐ No

Review the **Recommendations to Reduce Radiation Exposure to Others** (exit interview) with the patient if they are determined to be suitable candidate for outpatient treatments. Note: these are good practice guidelines.

RADIATION SAFETY TRAINING
IN-PATIENT IODINE THERAPY

Name:_____ **Date:**_____ **Instructed By:**_____

Patient Control

- Patient is admitted to room 233. Room is prepared by Nuclear Medicine.
- Nursing staff will follow normal admitting protocols.
- Radiologist will explain procedure to patient and obtain written consent.
- Nuclear Medicine Tech brings I-131 to room and doses patient.
- Patient does not leave room until released by Radiologist.

Visitor Control

- **NO VISITORS**

Contamination Control

- Nuclear Medicine Technologist will:
  1. Use leak proof absorbent paper to cover large surfaces that are likely to be contaminated. Smaller items may be covered with absorbent paper or plastic bags.
  2. Provide separate containers for linen, disposable waste, and non-disposable contaminated items.
  3. Urine will be discarded by release into the sewer system.
  4. Stock additional disposable gloves, absorbent paper, shoe covers, on a cart outside the room door for use as necessary by nursing, nuclear medicine, and radiation safety personnel.

- Nursing staff will:
  1. Order disposable food trays and utensils for the duration of the patient's stay. Inform the Housekeeping office that personnel should stay out of the room until otherwise notified.
  2. Ensure that **ONLY DISPOSABLE ITEMS** enter the room. This includes equipment for vital signs.
  3. Be responsible for ensuring that **nothing leaves the room.** All items used on the patient or by the patient must remain in the room until cleared by Nuclear Medicine.
  4. For each visit with the patient, the nurse will use the pocket dosimeter. Readings will be recorded on the log sheet along with room entry and exit times.
  5. Use contact isolation procedures.
  6. Use shoe covers.
  7. Hand washing must be done outside of the patient's room as the sink in that room will be contaminated.
  8. **UNDER NO CIRCUMSTANCE WILL PREGNANT PERSONNEL ENTER THE ROOM.**

EASTERN NEW MEXICO MEDICAL CENTER
405 West Country Club Road • Roswell, NM 88201-5265

Policy/Procedure Title	**RADIATION SAFETY DURING IODINE THERAPY OVER 30 mCi DONE AS AN IN-PATIENT**			**Policy #**	7060-13b
Manual Location(s)	Nuclear Medicine, Radiology, Imaging Center	**Effective**	12/22/99	**Page**	Page 1 of 3
Department Generating Policy	Nuclear Medicine		**JCAHO Function**		
Affected Departments	Nuclear Medicine				
Prepared By	Teresa Bersane, CNMT	**Date/Title**	Asst. Director, Radiology		
Approved By	Terry Anderson, RT(R)(CT)	**Date/Title**	Director Radiology		
Approved By	Phillip Durand, D.O.	**Date/Title**	Radiation Safety Officer		
Dept. / Committee Approval (If Applicable)		**Date/Title**			
Medical Staff Approval (If Applicable)		**Date/Title**			
Board Approval (If Applicable)		**Date/Title**			

I. PURPOSE

To establish procedures for radiation safety during Iodine therapy done with the patient hospitalized.

II. POLICY

Procedures for Iodine Therapy over 30 millicuries will meet the requirements of NMRPR subpart 7 section 708 as outlined in Appendix K. ✓

III. PROCEDURE

1. RADIATION SAFETY INSTRUCTION

Radiation safety instruction for all personnel caring for the hospitalized patient receiving radiopharmaceutical therapy will be provided. The instruction will describe procedures for:

--- Patient Control
--- Visitor Control
--- Contamination Control
--- Waste Control
--- Notification of the RSO in case of the patient's death or medical emergency.

Policy/Procedure Title	Radiation Safety During Iodine Therapy over 30 mCi	Policy #	7060-13b
Manual Location(s)	Nuclear Medicine	Page #	Page 3 of 3

l) Before using the room for general occupancy, it must be decontaminated and released to the admitting office. Remove all absorbent paper, and place it in the appropriate container. Transfer all containers to the storage room for decay. Use a survey meter to check for room contamination. Wipe tests will be performed to check for removable contamination. The room will be released when all wipe tests are below 200dpm/100 square cm. When the room is released, housekeeping will be notified that cleaning restrictions have been removed, and admitting will be notified that the room is available for use.

m) All documentation, (training records, exposure rate measurements, thyroid burden, etc.) will be kept in Nuclear Medicine files.

ATTACHMENT (s)
REFERENCE (S)

Original Effective Date:	12/22/99				
Reviewed and/or Revised Dates					
	1st	2nd	3rd	4th	5th
Review Date:		05/05/05	04/08/08		
Revised Date:	03/15/02				
Supersedes:					
By:	T.Bersane	T.Bersane	T. Bersane		

Policy/Procedure Title		Policy #	
Manual Location(s)		Page #	Page 2 of 2

Original Effective Date:	03/18/03				
	Reviewed and/or Revised Dates				
	1st	2nd	3rd	4th	5th
Review Date:	05/07/05	04/08/08			
Revised Date:					
Supersedes:					
By:	TCB	TCB			

Patient Label Here

Date:_____

Eastern New Mexico Medical Center
Nuclear Medicine Department

Patient Instructions for Immediate Release Following Administration of Iodine 131

The following written instruction along with additional verbal instructions are provided to ensure patients treated with unsealed radioactive materials and/or radioactive implants when released are given specific instructions how to keep the potential radiation exposure to other individuals as low as reasonably achievable.

Following this guidance will ensure that patients treated with radioactive materials have a low likelihood for a potential radiation exposure to any other individual at an effective dose equivalent of 1 mSv or 0.1 rem radiation exposure. Compliance with these instructions will ensure that potential radiation exposures to other individuals are kept As Low As Reasonably Achievable (ALARA) in compliance with Federal, State, and facility radioactive license conditions.

The therapy dose of Iodine 131 you receive will be taken up by thyroid tissue with the remaining dose eliminated from the body in fecal material, urine, sweat, tears, and saliva. The absorption and excretion of the radioactive dose presents unique challenges that need your focused attention and actions.

Routine questions or concerns should be directed to the Nuclear Medicine Department by calling 575-624-8761, Monday through Friday, 8 a.m. to 4 p.m. More emergent medical conditions should be directed to your family physician or to emergency services by calling 911.

The Radiation Safety Officer or his/her designee is available 24/7 to discuss radiation safety concerns. You can contact the RSO by calling the hospital operator at 575-622-8170 then ask to them to connect you.

Occupancy Factor:

E = 0.25 may be used, if the patient has been given the following instructions prior to release:

EASTERN NEW MEXICO MEDICAL CENTER

Patient Name:_____

Date of treatment:_____

I-131 Activity Administered_____

I-131 dose prescribed by_____**Authorized User**

I-131 dose administered by_____**Nuclear Medicine Technologist**

In Case of Emergency, Contact the Nuclear Medicine Department at 575-622-8170 ext 5384, Mon – Fri, 7:00 am to 3:00 pm. After those hours you may call 575-624-8761 and ask to speak to the RSO or a Nuclear Medicine Technologist.

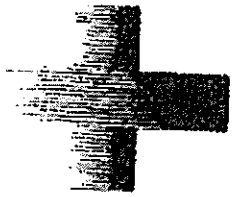
Policy/Procedure Title	Bioassays of staff who handle I-131	Policy #	7060-13
Manual Location(s)	Nuclear Medicine, Radiology	Page #	Page 2 of 2

a. Whenever the thyroid burden at the time of measurement exceeds 0.04 uCi of I-131, the following actions shall be taken:
   - An investigation of the operations involved, including ventilation surveys, shall be carried out to determine the causes of exposure and to evaluate the potential for further exposures.
   - If the investigation indicates that further work in the area might result in exposure of a worker to concentrations that are excessive, the licensee shall restrict the worker from further exposure until the source of exposure is discovered and corrected.
   - Corrective actions that will eliminate or lower the potential for further exposures shall be implemented.
   - A repeat bioassay shall be taken within one week of the previous measurement in order to confirm the effectiveness of the corrective action taken or to verify internal radioiodines present.
   - Reports or notification shall be provided as required by 20.3.4.452 NMAC.

b. If the thyroid burden at any time exceeds 0.14 uCi of I-131, the following actions shall be taken:
   - Prevent the individual from any further handling of I-131 until the thyroid burden is below the above limits; and
   - Carry out all steps above; and
   - As soon as possible, refer the case to appropriate medical consultation for recommendations regarding therapeutic procedures that may be carried out to accelerate removal of radioactive iodine from the body. This should be done within 2 to 3 hours after exposure when the time of exposure is known so that any prescribed thyroid blocking agent would be effective; and
   - Carry out repeated measurements at approximately one week intervals at least until the thyroid burden is less than 0.04 uCi of I-131.

ATTACHMENT (s)
REFERENCE (S)

Original Effective Date:					
	Reviewed and/or Revised Dates				
	1st	2nd	3rd	4th	5th
Review Date:					
Revised Date:					
Supersedes:					
By:					



Gerald Champion
Regional Medical Center
The Evolution of Excellence

Radiation Control Bureau
Margaret Roybal,

March 31,2010

I have attached the instructions we give the patients receiving therapeutic quantities of I131. We do not give any doses of I131 higher than 29.9 mCi. For the time period March 31 2005 through March 31, 2010 we have performed 95 I-131 therapies. If you need any more information please call (575) 443-7720.

Sincerely,

Karli A. Sorensen, CNMT, ARRT(N)
Lead Nuclear Medicine Technologist
Gerald Champion Regional Medical Center

Lovelace

This is what the patient is given

PATIENT INSTRUCTIONS FOLLOWING OUTPATIENT RADIOIODINE THERAPY (HIGH DOSE, OVER 30mCi I-131)

MEDICATIONS: Follow your doctor's instructions for resuming thyroid medications.

The dose of radioiodine you received is beneficial to you but it is desirable that the amount of radiation given to other people be minimized.

TO MINIMIZE THE RADIATION DOSE TO OTHER PEOPLE:

1. Keep away from other people (3 feet or more) for at least 72 hours. (3 days)
2. Sleep alone in a separate room for at least 72 hours.
3. Do not use mass transportation (plane, bus, train) for at least 72 hours.
4. Do not take a long trip in a car with other people for at least 72 hours.
5. You must have your own bathroom (not shared with other people) for at least 72 hours.
6. Keep away (at least 10 feet) from infants, young children and pregnant women for at least FOUR DAYS.
7. Avoid conception for at least 6 MONTHS.
8. Patient agrees to go straight home after receiving treatment

DIET

1. Drink plenty of fluids for at least 48 hours.
2. Chew gum or suck on hard candy to encourage the flow of saliva.
3. It helps to use disposable cups, plates, and table-wear for three days. If not rinse and wash them well separately after each use.

PERSONAL HYGIENE

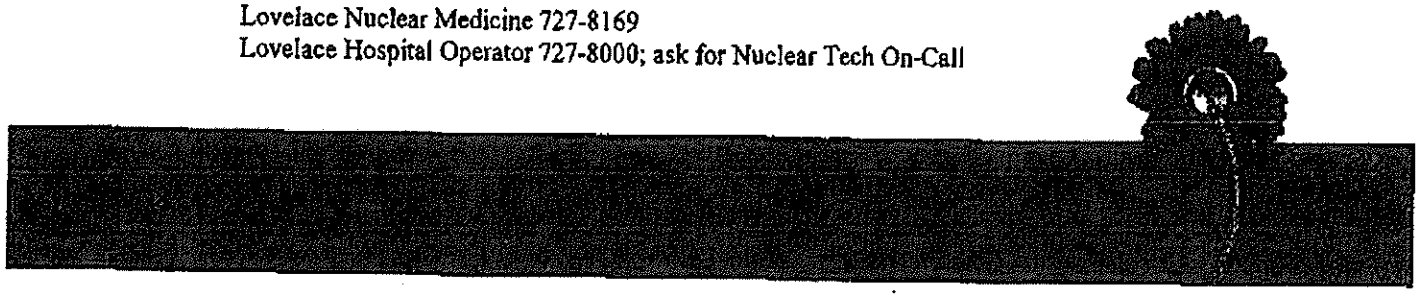
1. Urinate frequently (every two hours if possible) for three days. Your urine will be radioactive. Men should sit down to urinate so as not to splash.
2. Flush the toilet twice and wash your hands well.
3. Shower daily and use separate towels for three days.
4. Any clothes contaminated with urine should be washed separately.
5. After two or three days, you're bedding and linens should be washed separately.

IF PROBLEMS

1. In the rare case you should vomit within two hours of receiving the therapy, use toilet paper to soak up the material and flush it down the toilet.
2. If you experience any of these symptoms, contact your physician:
   INCREASED SHAKINESS
   RAPID HEART RATE
   SHORTNESS OF BREATH
   PAIN OR SWELLING IN THE NECK OVER THE NEXT 2-3 WEEKS
   DIFFICULTY BREATHING

CONTACTS

Lovelace Nuclear Medicine 727-8169
Lovelace Hospital Operator 727-8000; ask for Nuclear Tech On-Call



OUTPATIENT RADIOIODINE THERAPY WORKSHEET
(FOR HIGH DOSE, OVER 30 mCi. I-131)

Patient Name _____

Patient Number _____

Requesting Physician _____

Date _____

_____ Patient has completed and signed the "*Patient Agreement/Eligibility*" form

PATIENT SPECIFIC DOSE CALCULATIONS

Patient-specific dose calculations (Check 1 of the 3 boxes, whichever applies and calculate D).

□ For Na ^{131}I treatment of a patient *post-thyroidectomy* for thyroid cancer:
D (mrem) 2.27 Qo = _____ mrem,
where D (mrem) is the maximum likely dose to an individual exposed to the patient and Qo is the administered activity in millicuries (e.g., if you administer 100 mCi to the patient, then D (mrem) = 2.27 * 100 = 227 mrem).

□ For Na ^{131}I treatment of hyperthyroidism:
D (mrem) = 8.84 Qo = _____ mrem,
where D (mrem) is the maximum likely dose to an individual exposed to the patient and Qo is the administered activity in millicuries.

Note: the above 2 calculations use occupancy factors discussed in Appendix B, section B.1.2 of NRC Regulatory Guide 8.39, and and effective half-lives and uptake components found in Table B-1 of NRC Regulatory Guide B.39. If you use other values, as determined to your specific patient, you must use Equation B-5 of the Regulatory Guide. You must write the entire equation below:

□ D (mrem) =

Answer the following:

Yes	No	
□	□	The maximum likely dose to an individual exposed to the patient [D (mrem)] is less than 500 millirem?

If yes, the patient may be released. Keep this worksheet (including any other calculations) and a copy of the patient instructions for documentation of compliance with 10CFR 35.75.

This patient received a dose of _____ mCi 131 as therapy at _____ AM/PM on _____.

_____ The patient has been given a copy of "*Patient Instructions Following Outpatient Radioiodine Therapy* (high dose, over 30 mCi I-131)" and had read and understands that form.

_____ The patient's questions have been answered.

Nuclear Medicine Staff _____

I/Radiology/Admin/Admin Assist/Ruben

NUCLEAR MEDICINE INSPECTION RECORD

License Number_____
Expiration Date_____
Date of this Inspection_____
Inspection Priority_____
Previous Inspection Date_____

Type of Inspection: ____Routine ____ Announced ____Unannounced ____Initial _____Special

LICENSE NAME & ADDRESS ACTUAL LOCATION

TELEPHONE

MANAGEMENT AND PERSONNEL CONTACTED (Organizational chart (§109). Present at entrance and exit meetings, including ancillary personnel and those contacted by phone): **NOTE: Every attempt must be made to contact the highest ranking individual as possible.**
MANAGEMENT OVERSIGHT (RSO-702.B NMAC, RSC -§702.A NMAC and Authorized Users): Radiation Safety Committee, ALARA, Membership, Quarterly Meetings, and Annual Program Review):

SPECIAL LICENSE CONDITIONS (§308), (Program changes):

NMED Inspector Date of Report

Management Reviewer Date of Review

Letter sent to Licensee on:

FACILITY: (Design, Floor Plan, Control of Access, Security):

SHIELDING:

POSTING AND LABELING: [] NMED 045, [] License, [] Copy of Regulations, [] O & E Procedures, and [] Nuclear Medicine Tech Certification, [] Labeling of Containers, Vials and Syringes); [] RAM Radiation Area Signs):

MATERIAL USE AND CONTROL – §702 H: (Receipt and Opening of package(s) Inventory Log; Receiving Area; Normal Delivery Time(s); Package Surveys –Meter and Wipes):

SURVEY INSTRUMENTS AND CALIBRATION -§703 I.3 NMAC: (Operable and Calibrated Survey Equipment, Procedures. NOTE: (Range 0.5 mR/hr and 1 mR-1000 mR/hr with annual calibrations):

AREA RADIATION SURVEYS AND CONTAMINATION CONTROL - §703H.: (Survey Map, Action Levels, Wipe Analysis, PPE, and Records; (Survey each day of use with survey meter and wipes where prepared or administered and weekly where RAM are stored and reported in dpm or $\mu Ci/100\ cm^2$ for wipes): **NOTE: (REQUEST DEMONSTRATION)**

LEAK TEST (§415): (>100 μCi Beta, Gamma; > 10μCi Alpha): (Wipe Test Analyses, Authorized by License Condition or Vendor Certification). **NOTE: Request a Wipe Test Demonstration.**

ENVIRONMENTAL CONTROLS: (Xenon-133 and/or Iodine 131), Air Concentration Monitors, Engineered Controls (i.e., Hoods, Filters and Charcoal Traps, Ventilation Calculations, and Negative Pressure): (NOTE: Charcoal Filter -- Dryrite should be Blue, not Pink or White):

TRANSPORTATION/ SHIPPING: (DOT Regulations, Quantities and Types Shipped, Dose or Sealed Sources, Returns, Procedures for Monitoring Radiation and Contamination Levels of Packages, Action levels, and Hazmat Training Records):

NOTIFICATIONS OF INCIDENTS AND EVENTS AND REPORTS, (Theft, loss, Incidents, Overexposures, Change in RSO or Authorized Users):

INDEPENDENT AND CONFIRMATORY MEASUREMENTS: (Areas surveyed, comparison of data with licensee's results and regulations). NOTE: Attach supporting documentation.

Background _____ Area Map Used _____
NMED Instrument Used _____ Model # _____ Calibration Date _____

Signature of Exit Interview Representative_____

OUTPATIENT RADIOIODINE THERAPY WORKSHEET
(FOR HIGH DOSE, OVER 30 mCi. I-131)

Patient Name _____

Patient Number _____

Requesting Physician _____

Date _____

_____ Patient has completed and signed the "*Patient Agreement/Eligibility*" form

PATIENT SPECIFIC DOSE CALCULATIONS

Patient-specific dose calculations (Check 1 of the 3 boxes, whichever applies and calculate D).

□ For Na ^{131}I treatment of a patient *post-thyroidectomy* for thyroid cancer:
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D (mrem) = 8.84 Qo = _____ mrem,
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Answer the following:

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_____ The patient's questions have been answered.

Nuclear Medicine Staff _____

PRESBYTERIAN HOSPITAL
ALBUQUERQUE, NEW MEXICO

Treatment Permit for Administration of Radioactive Iodine
to treat Thyroid Cancer in Non-hospitalized Patients

I request and authorize _____ to administer _____ mCi radioactive iodine by mouth for the treatment of thyroid cancer. The purpose of the treatment is to destroy cancer cells in the irradiated target tissues and tumor to decrease the chances of recurrence. I understand that normal tissue as well as the tumor will be treated. This radiation may cause damage to bone marrow, kidneys, or lungs, resulting in lowering of the blood counts or scar tissue or both. I understand that this scar tissue might cause symptoms in the future, some of which, in rare circumstances, could require surgical correction.

I understand that in addition to general symptoms and side effects, such as nausea, occasional vomiting, stomach pain, diarrhea, and increased fatigability, the following specific symptoms and side effects may occur as a result of the prescribed treatment:

Acute reactions during treatment including but not limited to:

Pain in the salivary glands, loss of taste, dry mouth, sore throat and hoarseness

Temporary lowering of white blood count which could predispose to infection

Late reactions after treatment including but not limited to:

Possibility of causing cancer in the future and permanent lowering of blood counts

I understand that no guarantee is made as to the outcome of this treatment of the course of my disease

I also understand and agree to the precaution and isolation procedures explained to me as necessary measures to minimize radiation exposure to other persons. I understand in agreeing to this outpatient, homebound, isolation arrangement that I am responsible for insuring minimal exposure to others by adhering to the isolation procedures explained in detail both orally by the Nuclear Medicine department staff, and in written form as provided by instruction sheets.

I have been informed and I understand that if I change my mind and do not want to be treated further, treatments will be stopped. I have been given the opportunity to ask questions about this procedure and all my questions have been answered to my satisfaction.

I am not breastfeeding. To the best of my knowledge I am not pregnant.

I have read the above, which was fully explained to me, and I give my informed consent.

SIGNED (Person authorized to give consent)	WITNESS	DATE

I (we) have personally described and explained the nature of the procedure and the risks and consequences that are involved, alternative procedures, if any, and the risks and consequences involved, in layman's language, to the patient upon whom it is to be performed before the patient signed this authorization and consent.

PHYSICIAN	NUCLEAR MEDICINE TECH.	DATE